

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: INSULIN PRICING LITIGATION

Case 2:23-md-03080 (BRM) (RLS)
MDL No. 3080

JUDGE BRIAN R. MARTINOTTI
JUDGE RUKHSANAH L. SINGH

THIS DOCUMENT RELATES TO: 25-cv-01845

**MEMORANDUM IN SUPPORT OF THE GOVERNMENT OF PUERTO RICO'S
MOTION FOR LEAVE TO AMEND COMPLAINT**

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NOW COMES Plaintiff, the Government of Puerto Rico (“Puerto Rico” or the “Government”), through its undersigned counsel, and respectfully moves the Court for leave to amend its Complaint pursuant to Rules 16(b)(4) and 15(a)(2) of the Federal Rules of Civil Procedure.

INTRODUCTION

Rule 16(b)(4) allows the case schedule to be modified for good cause with the court’s consent and Rule 15(a)(2) provides that courts should “freely give leave when justice so requires.” Fed. R. Civ. P. 16(b)(4); Fed. R. Civ. P. 15(a)(2). This action was recently transferred to this Court and is still in the initial stages of litigation. Prior to transfer to this multidistrict litigation (“MDL”), no court issued a case management or scheduling order, and discovery had not yet begun (not even the initial disclosures provided for in Fed. R. Civ. P. 16). Moreover, no court ruling has addressed the merits of the Government’s claims, whether by a Fed. R. Civ. P. 12 motion or otherwise.

The Government’s proposed Second Amended Complaint (“SAC”) (attached as Exhibit A) amends the Government’s complaint in two ways. First, it conforms to the allegations at issue in this MDL, including: (1) adding allegations concerning glucagon-like peptide receptor agonists (“GLP-1s”); (2) adding the PBM Defendants’¹ group purchasing organizations (Ascent Health Services LLC, Emisar Pharma Services LLC, and Zinc Health Services, LLC) as defendants; and (3) adding additional detail and clarification regarding the Insulin Manufacturer Defendants’² deceptive practices (*e.g.*, the publication of artificially inflated list price, the act of artificially

¹ “PBM Defendants” refers to Defendants CaremarkPCS Health LLC, Caremark Puerto Rico LLC, Express Scripts, Inc., and OptumRx, Inc.

² “Manufacturer Defendants” refers to Defendants Eli Lilly and Company, Eli Lilly Exports S.A., Novo Nordisk, Inc., Sanofi-Aventis U.S. LLC, and Sanofi-Aventis Puerto Rico, Inc.

inflating list prices). Second, it adds claims against the PBM Defendants, including: (1) the PBM Defendants' unfair and deceptive practices and unfair methods of competition that artificially increase the cost of all brand-name drugs, not only insulin or GLP-1 products; and (2) the PBM Defendants' pharmacy-related practices that harm competition in the pharmacy market and disadvantage independent pharmacies. For example, the SAC alleges that the list price for Humira, AbbVie's blockbuster rheumatoid arthritis drug, increased over 78% from 2015 to 2019; however, most of that increase was attributable to rebates—which grew over 600% in large part due to the PBM Defendants' unfair and deceptive rebate and formulary practices. SAC ¶ 102. It also alleges that the PBM Defendants pay low reimbursement rates to independent pharmacies for lower-margin drugs while also steering higher-margin drugs to PBM Defendants' own pharmacies. *Id.* ¶¶ 190–215.

Allowing the Government to simultaneously litigate its insulin and non-insulin claims is the most efficient path forward. Because the Government's request comports with Rules 16(b)(4) and 15(a)(2), the Court should grant the Government leave to file its Second Amended Complaint.

BACKGROUND

A. The Government's Action Is in Its Initial Stages.

On January 17, 2023, the Government filed an action in Puerto Rico State Court (known as the Court of First Instance) against the PBM Defendants and Manufacturer Defendants to punish, stop, and deter violations of Puerto Rico's Fair Competition Act, 10 L.P.R.A § 259. On

January 24, 2023, the Government filed an Amended Complaint to correct minor factual errors. DPR Dkt. No. 1-1.³

On March 17, 2023, Defendant Express Scripts, Inc. (“Express Scripts”) removed the case to the District of Puerto Rico, asserting federal officer jurisdiction under 28 U.S.C. § 1442(a)(1), on the grounds that it provided PBM services for a federal government health care program. DPR Dkt. No. 1 at 1. Defendants CaremarkPCS Health, LLC and Caremark Puerto Rico LLC (together, “Caremark”) thereafter joined in the removal on the same grounds with a slightly different theory. DPR Dkt. No. 4 at 1–2. On July 13, 2023, the District Court of Puerto Rico granted the Government’s motion and remanded this matter to the Court of First Instance. DPR Dkt. Nos. 102–103. Shortly thereafter, Caremark and Express Scripts appealed to the First Circuit. DPR Dkt. No. 104.

As both the District Court and the First Circuit denied the Defendants’ motions to stay pending appeal, the case eventually returned to the Court of First Instance. On October 5, 2023, the Government propounded discovery requests to the PBM Defendants. On the eve of the deadline for responding to the Government’s discovery requests, however, the PBM Defendants filed a motion to stay proceedings pending the outcome of their First Circuit appeals, or in the alternative, of their recently-filed motion to dismiss in the Court of First Instance. As a practical matter, then, the PBM Defendants unilaterally refused to produce any documents until the Court of First Instance ruled on their motion to stay—which the court never did.

³ References to “Dkt. No.” are to the docket in Case No. 25-cv-01845, references to “DPR Dkt. No” are to the docket in Case No. 3:23-cv-01127, and references to “JPML Dkt. No.” are to the Judicial Panel on Multidistrict Litigation’s docket in MDL No. 3080.

On October 18, 2024, the First Circuit reversed the District Court's remand ruling and ordered the return of the case to the District of Puerto Rico for further proceedings. DPR Dkt. No. 117 at 5. The Court of First Instance did not rule on the motions to stay or the motions to dismiss; did not issue any case management or scheduling orders; and did not set forth any deadlines—particularly with respect to amending the complaint—before the case headed back to federal district court.

B. The Government Sought Leave to Amend Its Complaint Shortly After the First Circuit's Order Reopening Proceedings in the District Court.

On December 6, 2024, the District Court issued an order reopening its proceedings. Shortly thereafter, on December 20, 2024, the Government moved to amend its complaint to add non-insulin claims. Dkt. Nos. 122, 127.

On December 31, 2024, the Government filed a Motion to Vacate Conditional Transfer Order 21 (“Motion to Vacate”), as Caremark had filed a Notice of Potential Tag-Along Action on November 13, 2024. JPML Dkt. Nos. 345, 359. On January 6, 2025, the Manufacturer Defendants filed a response in support of the Government’s Motion to Vacate. JPML Dkt. No. 374.

On January 27, 2025, the District of Puerto Rico denied the Government’s Motion for Leave to Amend Complaint as untimely, even though the Court had not even issued an initial case management or set forth any case-related deadlines. Instead, the Court summarily concluded that the Government was seeking to amend its Complaint solely to avoid transfer to this MDL. DPR Dkt. No. 147. The next day, on January 28, 2025, the Government filed a motion with the District of Puerto Rico to seek clarification as to whether its denial of the Government’s Motion for Leave to Amend Complaint was without prejudice. DPR Dkt. No. 149.

On March 5, 2025, the District Court denied the Government’s Motion for Clarification but stated: “The Court denied leave to amend the complaint as untimely. *It did not adjudicate or*

comment on the merits of the claims in the proposed Second Amended Complaint and the Order was not a final judgment on any claim.” DPR Dkt. No. 163 (emphasis added).

On March 10, 2025, the Government withdrew its Motion to Vacate.

On March 13, 2025, the Government’s action was transferred to this MDL.

ARGUMENT

A. Good Cause Exists to Modify the Scheduling Order

As of the date this matter was transferred into this MDL, the deadline for amending the pleadings in the MDL had already expired. Prior to transfer, the Government’s action was effectively stayed during the pendency of Caremark’s and Express Scripts’ appeals, no case management deadlines had been set, and discovery had not yet begun. Thus, unlike the other State Attorneys General in this MDL, the Government has not had a good-faith opportunity to amend its complaint prior to the expiration of the deadline for amendment of the pleadings despite its diligence.

Good cause exists under Rule 16 if the movant shows that its delay in filing the motion to amend stemmed from “any mistake, excusable neglect or any other factor which might understandably account for failure of counsel to undertake to comply with the Scheduling Order.” *Fermin v. Toyota Material Handling, U.S.A., Inc.*, 2012 WL 1393074, at *3 (D.N.J. Apr. 23, 2012). Good cause exists here because the Government’s action was transferred into the MDL after the expiration of the deadline for amendment of the pleadings. The Court should therefore grant the Government leave to amend its complaint pursuant to the liberal amendment policy of Rule 15(a)(2). *See, e.g., Dole v. Arco Chem. Co.*, 921 F.2d 484, 486–87 (3d Cir. 1990) (“[W]e have held consistently that leave to amend should be granted freely. . . . This approach ensures that a particular claim will be decided on the merits rather than on technicalities.”).

B. The Government Should be Freely Given Leave to Amend Its Complaint Pursuant to Rule 15(a)(2)

In *Foman v. Davis*, 371 U.S. 178, 182 (1962), the Supreme Court held that leave to amend should be “freely given” pursuant to the plain language of Rule 15(a)(2) when there is no evidence of undue delay, bad faith, a dilatory motive, undue prejudice, or futility of the amendment. Courts have shown “a strong liberality” in allowing amendment under Rule 15(a), using prejudice to the non-moving party as a “touchstone” for denial of amendment. *Bechtel v. Robinson*, 886 F.2d 644, 652 (3d Cir. 1989). To establish prejudice, the non-moving party must show “it was unfairly disadvantaged or deprived of the opportunity to present facts or evidence which it would have offered had the . . . amendments been timely.” *Id.* The non-moving party bears the burden of showing actual prejudice. *See, e.g., Leibholz v. Robert Hariri and Celgene Corp.*, 2007 WL 2177386, at *6 (D.N.J. July 27, 2007).

None of the *Foman* factors that would support a denial of a motion to amend are present here. This action is still in the beginning stages of litigation. The parties spent almost two years litigating jurisdictional issues. DPR Dkt. No. 122. Prior to transfer to this MDL, there were no rulings on the merits of this litigation, no discovery, and no scheduling or case management orders in this matter. Generally, courts in the District of New Jersey have not found unfair prejudice when a party moves to amend while discovery is still open—let alone when, as here, discovery has not yet begun. *See e.g., Luppino v. Mercedes-Benz USA, LLC*, 2014 WL 4474004, at *4 (D.N.J. Sept. 4, 2014); *see also In re Takata Airbag Prods. Liab. Litig.*, 379 F. Supp. 3d 1333, 1339 (S.D. Fla. 2019) (“[M]any transferee courts have allowed plaintiffs to amend a transferred-in complaint to add new causes of action at early stages in the proceedings.”). Even if the Government had amended its complaint earlier, this litigation would still be exactly where it is now—at the very beginning—because, as explained above, this matter was effectively

stayed during the pendency of Caremark's and Express Scripts' appeals. Having refused to respond to discovery while the case was pending in the District of Puerto Rico, Defendants cannot now claim to have been disadvantaged by an amendment of the complaint; instead, they had the benefit of a two-year self-help stay. Nothing in the Government's SAC would have changed Defendants' obligations in the interim. Moreover, Defendants cannot claim to be prejudiced by the amendments seeking to conform the Government's complaint to the existing allegations in the MDL, since those allegations are already the subject of discovery and well within the scope of the MDL. For these reasons, the Government's amendment will not cause undue delay or prejudice to Defendants.

In addition, the new allegations in the SAC are largely based on information that was not available when the Government initiated this action or a week after that when the Government filed its First Amended Complaint to correct minor factual errors. For example, in the SAC, the Government cites to the following documents:

- market analysis published on April 2, 2024 concerning the cost benefits to health plans of preferring Humira biosimilars on their formularies rather than Humira (SAC ¶ 214 n.141)
- the Federal Trade Commission's interim report published in July 2024 titled: "Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies" (*Id.* ¶ 223 n.149)
- news article published on November 7, 2024 detailing audit finding relating to OptumRx reimbursing independent pharmacies at a lower rate than its affiliated pharmacies (*Id.* ¶ 158)

Thus, the Government could not have added these allegations when it filed the original complaint or its First Amended Complaint.

C. The Law of the Case Doctrine Does Not Preclude This Court from Granting the Government Leave to Amend Its Complaint

The District of Puerto Rico’s denial of the Government’s previous Motion for Leave to Amend Complaint does not bar this Court from granting the Government’s Motion. Contrary to the PBM Defendants’ representations, Dkt. No. 560 at 2, “[t]he . . . doctrine does not restrict a court’s power but rather governs its exercise of discretion.” *In re Pharmacy Benefit Managers Antitrust Litig.*, 582 F.3d 432, 439 (3d Cir. 2009). As the Third Circuit explained: “A court has the power to revisit prior decisions of its own or of a coordinate court *in any circumstance*, although as a rule courts should be loathe to do so in the absence of extraordinary circumstances[.]” *Id.* (emphasis added). The Third Circuit has recognized “several” such extraordinary circumstances. *Id.*

First, the law of the case doctrine is generally inapplicable to decisions that are “avowedly preliminary or tentative.” *Greco v. Grewal*, 2020 WL 7334194, at *8 (D.N.J. Dec. 11, 2020) (Martinotti, J.). The District of Puerto Rico’s earlier ruling was just such a decision. That court plainly stated its decision was not an adjudication on the merits or a final judgment. DPR Dkt. No. 147. Rather, the Court found the Government’s Motion untimely in the context of the impending transfer to this MDL—specifically, the Court expressed concern that the Government’s amendment was an attempt to escape the MDL’s jurisdiction. *Id.* The subsequent transfer of this matter obviates that concern.

Second, the law of the case doctrine does not preclude a judge from clarifying or correcting an earlier, ambiguous ruling. *Id.* The District Court’s order denying the Government’s Motion for Leave to Amend Complaint was ambiguous. *See* DPR Dkt. No. 149.

The Government filed a Motion for Clarification to seek clarification on whether the order was with or without prejudice to the Government renewing its claims at a later time; however, the District Court denied it. *Id.* Moreover, judges have “the discretion to reconsider an issue and should exercise that discretion whenever it appears that a previous ruling, even if unambiguous, might lead to an unjust result.” *In re PBMs Antitrust Litig.*, 582 F.3d at 439. For all the reasons explained above, denying the Government leave to amend its complaint before this case has begun in earnest would be unjust.

Third, the District Court’s decision is “clearly erroneous and would work a manifest injustice.” *Kennon v. Johnson*, 2019 WL 413537, at *17 (D.N.J. Feb. 1, 2019) (Martinotti, J.). Respectfully, the District Court was wrong to consider the possibility of a forum shopping when deciding whether to grant the Government leave to amend its complaint or to view such a possible action as wrongful gamesmanship or bad faith. *See, e.g., Royal Canin U.S.A., Inc. v. Wullsleger*, 604 U.S. 22, 42 n.9 (2025) (dismissing “forum-manipulation concerns” where plaintiff amended complaint post removal to delete all federal-law claims; “First, and most practically, plaintiffs can usually forum shop without any resort to amendments.”); *see also Parker v. Exterior Restorations, Inc.*, 601 F. Supp. 3d 1221, 1227–28 n.5 (S.D. Ala. 2022) (rejecting argument that forum manipulation is properly considered under Rule 15(a)(2)). The District Court was also incorrect that the PBM Defendants would be unfairly prejudiced by the Government’s amendment, because it “expand[ed] the scope of the litigation and requir[ed] Defendants to litigate the claims relating to insulin prices in 2 different forums,” not because it would require the reopening of discovery or undue delay. DPR Dkt. No. 147. As explained above, this ruling is inconsistent with this district’s approach to amendments. Further, the Government is not aware of any authority to support such a begrudging interpretation of Rule 15(a).

Moreover, allowing the Government to move forward in the same proceeding with its insulin and non-insulin claims is the most efficient path forward for all parties. The Government could pursue its SAC outside the MDL and coordinate relevant discovery with the MDL plaintiffs.⁴ Alternatively, the Court could permit the Government to amend its complaint to add non-insulin claims but stay that portion of the case, preserving the Government's right to pursue these claims upon transfer to the District of Puerto Rico for trial or in a separate proceeding. This approach would allow the Government to conduct discovery on issues common to both its insulin and non-insulin claims (e.g., PBM Defendants' organizational structure and general rebate and formulary practices) within the MDL with no additional burden to Defendants or this Court.

CONCLUSION

For the foregoing reasons, the Government respectfully requests this Court issue an Order granting this Motion and permitting the Government to file its SAC.

DATED: June 6, 2025

RESPECTFULLY SUBMITTED,

DEPARTMENT OF JUSTICE OF PUERTO RICO

/s/ Elizabeth Paige Boggs

LINDA SINGER

Admitted *Pro Hac Vice*

DAVID I. ACKERMAN

ELIZABETH PAIGE BOGGS

Admitted *Pro Hac Vice*

DEVIN X. WILLIAMS

Admitted *Pro Hac Vice*

MOTLEY RICE LLC

401 9th Street, NW, Suite 630

Washington, DC 20004

Tel. (202) 386-9626

Fax. (202) 386-9622

lsinger@motleyrice.com

dackerman@motleyrice.com

⁴ The Judicial Panel on Multidistrict Litigation has ruled that actions with allegations beyond insulin are not appropriate for inclusion in this MDL. *See* MDL No. 3080, Dkt. No. 259.

pboggs@motleyrice.com
dwilliams@motleyrice.com

ANDRÉS W. LÓPEZ
Admitted *Pro Hac Vice*
THE LAW OFFICES OF
ANDRÉS W. LÓPEZ, P.S.C.
P.O. Box 13909
San Juan, PR 00908
Tel. (787) 294-9508
andres@awllaw.com